

*Competitive acquisition program (CAP)* means a program as defined under section 1847B of the Act.

*Designated carrier* means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

*Drug* means both drugs and biologicals.

*Emergency delivery* means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

*Emergency situation* means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of §414.906(e) are met.

*Local carrier* means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

*Manufacturer's average sales price* means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

*Multiple source drug* means a drug described by section 1847A(c)(6)(C) of the Act.

*Pacific Territories* means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

*Participating CAP physician* means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the

CAP must agree to accept assignment for CAP drug administration claims.

*Participating CAP physician election agreement* means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

*Prescription order* means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

*Routine delivery* means delivery of a drug within 2 business days in appropriate shipping and packaging in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and packaging. In each case, this timeframe will be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.

*Single source drug* means a drug described by section 1847A(c)(6)(D) of the Act.

*Timely delivery* means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

*Unit* is defined as in part 414, subpart J of this chapter.

*Wholesale acquisition cost (WAC)* means the price described by section 1847A(c)(6)(B) of the Act.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005]

#### **§414.904 Average sales price as the basis for payment.**

(a) *Method of payment.* Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

(1) The actual charge on the claim for program benefits; or

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(b) *Multiple source drugs*—(1) *Average sales prices.* The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(c) *Single source drugs*—(1) *Average sales price.* The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) *Limitations on the average sales price*—(1) *Wholesale acquisition cost for a single source drug.* The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient.* (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in CY 2006 and subsequent calendar years, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is the amount determined under section 1847A of the Act.

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by 5 percent or more in CYs 2005, 2006, 2007, 2008 2009, and 2010, the payment limit in the quarter following the transmittal of this information to the Secretary is the lesser of the widely available market price or 103 percent of the average manufacturer price.

(e) *Exceptions to the average sales price—(1) Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as determined by the Secretary), pneumococcal vaccine, and influenza vaccine and are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003 and is not updated in 2006.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment limit in a case where the average sales price during the first quarter of sales is unavailable.* In the case of a drug during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price for the drug, the payment limit is based on the wholesale acquisition cost or the applicable Medicare Part B drug payment methodology in effect on November 1, 2003.

(5) *Treatment of certain drugs.* Beginning with April 1, 2008, the payment amount for—

(i) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(A) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(ii) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(A) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for infusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 70332, Nov. 21, 2005; 71 FR 69788, Dec. 1, 2006; 72 FR 66402, Nov. 27, 2007; 73 FR 69937, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62012, Nov. 25, 2009]

#### § 414.906 Competitive acquisition program as the basis for payment.

(a) *Program payment.* Beginning in 2006, as an alternative to payment under § 414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in § 414.908(b).